

## CDER New Molecular Entity (NME) Drug and New Biologic Approvals for Calendar Year 2009

Updated through May 31, 2009

### NME New Drug Application (NDA) Approvals:

Application Type	Application Number	Proprietary Name	Established Name	Applicant	Review Classification	Approval Date	Indications
N	022256	SAVELLA	MILNACIPRAN HYDROCHLORIDE	CYPRESS BIOSCIENCE	S	14-Jan-09	PROVIDES FOR THE TREATMENT OF FIBROMYALGIA SYNDROME
N	021856	ULORIC	FEBUXOSTAT	TAKEDA	S	13-Feb-09	PROVIDES FOR THE CHRONIC MANAGEMENT OF HYPERURICEMIA IN PATIENTS WITH GOUT.
N	022334	AFFINITOR	EVEROLIMUS	NOVARTIS	P	30-Mar-09	PROVIDES FOR THE TREATMENT OF ADVANCED RENAL CELL CARCINOMA
N	022268	COARTEM	ARTEMETHER/ LUMEFANTRINE	NOVARTIS	P,O	07-Apr-09	PROVIDES FOR THE TREATMENT OF INFECTIONS DUE TO PLASMODIUM FALCIPARUM OR MIXED INFECTIONS INCLUDING P.FALCIPARUM
N	022129	PHYXXLICE	BENZYL ALCOHOL	SCIELE PHARMA	S	09-Apr-09	PROVIDES FOR PATIENTS INFECTED WITH PEDICULUS HUMANUS CAPITIS (HEAD LICE) OF THE SCALP HAIR
L	125289	SIMPONI	GOLIMUMAB	CENTOCOR ORTHO BIOTECH	S	24-Apr-09	PROVIDES FOR THE TREATMENT OF RHEUMATOID ARTHRITIS, PSORIATIC ARTHRITIS, AND ANKYLOSING SPONDYLITIS.
L	125274	DYSPOPT	ABOBOTULINUMTOXIN A	IPSEN BIOPHARM	S	29-Apr-29	PROVIDES FOR TREATMENT OF CERVICAL DYSTONIA (SPASMODIC TORTICOLLIS)
N	022192	FANAPT	ILOPERIDONE	VANDA PHARMS INC	S	06-May-09	PROVIDES FOR THE ACUTE TREATMENT OF SCHIZOPHRENIA IN ADULTS.
N	022275	SAMSCA	TOLVAPTAN	OTSUKA AMERICA PHARM	S	19-May-09	PROVIDES FOR THE TREATMENT OF CLINICALLY SIGNIFICANT HYPERVOLEMIC AND EUVOLEMIC HYPONATREMIA INCLUDING PATIENTS WITH SAIDH, HEART FAILURE, AND CIRRHOSIS.
N	022308	BESIVANCE	BESIFLOXACIN	BAUSCH AND LOMB	S	28-May-09	PROVIDES FOR THE TREATMENT OF BACTERIAL CONJUNCTIVITIS.

#### THERAPEUTIC POTENTIALS:

P - PRIORITY REVIEW - SIGNIFICANT IMPROVEMENT COMPARED TO MARKETED PRODUCTS, IN THE TREATMENT, DIAGNOSIS, OR PREVENTION OF A DISEASE.

S - STANDARD REVIEW - THE DRUG APPEARS TO HAVE THERAPEUTIC QUALITIES SIMILAR TO THOSE OF ONE OR MORE ALREADY MARKETED DRUGS.

O - ORPHAN DESIGNATION- PURSUANT TO SECTION 526 OF THE ORPHAN DRUG ACT (PUBLIC LAW 97-414 AS AMENDED).